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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,990	01/30/2002	Yizhong Gu	PB0176	6593

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	8

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/060,990	Applicant(s) GU ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement. ✓

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 8-11, 32, 33, and 39, drawn to an isolated nucleic acid, probe, vector, and host cell, classified in class 536, subclasses 23.1 and 24.3 and class 435, subclasses 320.1, 325 and 252.3. If this Group is elected, then the below summarized sequence election is required.

II. Claim 7, drawn to a microarray, classified in 435, subclass 287.2. If this Group is elected, then the below summarized sequence election is required.

III. Claim 12, drawn to a method for producing a polypeptide, classified in class 435, subclass 69.1. If this Group is elected, then the below summarized sequence election is required.

IV. Claims 13-18, 34, 35, and 40, drawn to an isolated polypeptide and fusion protein in classes 530 and 435, subclasses 350 and 69.7, respectively. If this Group is elected, then the below summarized sequence election is required.

V. Claims 19, 36-38, and 41, drawn to an antibody or antigen-binding fragment, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is required.

VI. Claims 20 and 21, drawn to a transgenic non-human animal, classified in class 800, subclass 14. If this Group is elected, then the below summarized sequence election is required.

VII. Claims 22 and 23, drawn to a method of identifying agents that modulate the expression of RGL3, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized specie election is also required.

VIII. Claims 24 and 42, drawn to an agonist of a polypeptide, classified in class 514, subclass 1. If this Group is elected, then the below summarized sequence election is required.

IX. Claims 25 and 43, drawn to an antagonist of a polypeptide, classified in class 514, subclass 1. If this Group is elected, then the below summarized sequence election is required.

X. Claims 26 and 27, drawn to a method of identifying a specific binding partner for a polypeptide, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.

XI. Claim 28, drawn to a purified binding partner of a polypeptide, classified in class 514, subclass 1. If this Group is elected, then the below summarized sequence election is required.

XII. Claim 29, drawn to a method for detecting a target nucleic acid in a sample, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.

XIII. Claim 30, drawn to a method of diagnosing a disease caused by mutation in RGL3, classified in class 436, subclass 64. If this Group is elected, then the below summarized sequence election is required.

XIV. Claim 31, drawn to a method of diagnosing or monitoring a disease by altered expression of RGL3, classified in class 436, subclass 64. If this Group is elected, then the below summarized sequence election is required.

XV. Claims 44-47, drawn to a method for treating or preventing a disorder associated with decreased expression or activity of RGL3 by modulating the gene of RGL3, classified in class 514, subclasses 2 and 44. If this Group is elected, then the below summarized sequence election is required.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See, for example, Figures 1A-1D. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because Figures 1A-1D, contain amino acid sequences with sequence lengths that are equal to or greater than 4 amino acid molecules and these sequences do not have SEQ ID Nos cited along with each sequence in the specification or Figure. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy for the

specification, statements under 37 CFR § 1.821(f) and (g), if there is a need to list additional sequences in the listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Sequence Election Requirement Applicable to All Groups:

4. In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group draw to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

5. Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

SPECIE ELECTION REQUIREMENT

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

7. **FOR GROUPS VII and XV (Species A)**

Species A1: Unspecified composition

Species A2: Nucleic acid

Species A3: Polypeptide

Species A4: Antibody

Species A5: Agonist

Species A6: Antagonist

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 22 is generic. These species are distinct due to the distinct critical feature of each species. It is noted that these species are utilized in both groups although only cited specifically in Group XV.

9. Applicant is advised that a reply to this requirement must include an identification of a specie from list of species cited above that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. The inventions of Groups [I, III, VII (nucleic acid), XII, XIII, XIV, and XV (nucleic acid)]; II; [IV, VII (polypeptide), X, XI, and XV (polypeptide)]; [V, VII (antibody), and XV (antibody)]; VI; VIII; and IX are distinct inventions because they are directed to different chemical types or methods regarding the critical limitations therein. For Groups I, III, VII (nucleic acid), XII, XIII, XIV, and XV, the critical feature is a nucleic acid. For Group II, the critical feature is a microarray. For Groups IV, VII (polypeptide), X, XI, and XV (polypeptide), the critical feature is a polypeptide. For Groups V, VII (antibody), and XV (antibody), the critical feature is an antibody. For Group VI, the critical feature is a transgenic non-human animal. For Groups VIII, VII (agonist), and XV (agonist), the critical feature is an agonist. For Groups IX, VII (antagonist), and XV (antagonist), the critical feature is an antagonist. Further, it is acknowledged that various processing steps may cause a polypeptide of the claims in Group IV and antibody of the claims in group V to be directed as to its synthesis by a nucleic acid set forth in Group I, however, the completely distinct critical features of each Group of inventions support the undue search burden if they were examined together. Additionally, the inventions as

directed to their respective compositions and their methods of use listed above have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately.

13. Inventions in Groups I, III, VII (nucleic acid), XII, XIII, XIV, and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the nucleic acid molecule of Group I may be utilized in the distinct usages as needed in Group III, a method for producing a polypeptide. As needed in Group VII (nucleic acid), a method for identifying agents that modulate the expression of RGL3. As needed in Group XII, a method for detecting a target nucleic acid in a sample. As needed in Group XIII, a method for diagnosing a disease caused by mutation in RGL3. As needed in Group XIV, a method of diagnosing or monitoring a disease by altered expression of RGL3. As in Group XV (nucleic acid), which is a method for treating or preventing a disorder associated with decreased expression or activity of RGL3. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

14. Inventions in Groups IV, VII (polypeptide), X, XI, and XV (polypeptide) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the polypeptide of Group IV may be utilized in the distinct usages as needed in Group VII (polypeptide), a method for identifying agents that modulate the expression of RGL3. As needed in Group X, a method of identifying a specific binding partner for a polypeptide. As in Group XI, which is a binding partner of a polypeptide. As needed in XV (polypeptide), which is a method for treating or preventing a disorder associated with decreased expression or activity of RGL3. As in or alternatively, a polypeptide may be used in a method for determining the degree of affinity between a ligand and its respective receptor in competitive binding assays, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

15. Inventions in Groups V, VII (antibody), and XV (antibody) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the antibody of Group V may be utilized in the distinct usages as needed in VII (antibody), which is a method for identifying agents that modulate the expression of RGL3. As needed in Group XV (antibody), a method for treating or preventing a disorder associated with decreased expression or activity of RGL3, or alternatively, an antibody may be used in a method for determining the localization of specific polypeptides, for example. All of these usages are distinct as requiring

distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

16. Inventions in Groups VIII, VII (agonist), and XV (agonist) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the agonist of Group VIII may be utilized in the distinct usages as in VII (agonist), which is a method for identifying agents that modulate the expression of RGL3. As needed in Group XV (agonist), a method for treating or preventing a disorder associated with decreased expression or activity of RGL3, or alternatively, an agonist may be used in a method for competitive binding assays, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

17. Inventions in Groups IX, VII (antagonist), and XV (antagonist) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the antagonist of Group IX may be utilized in the distinct usages as in VII (antagonist), which is a method for identifying agents that modulate the expression of RGL3. As needed in Group XV (antagonist),

a method for treating or preventing a disorder associated with decreased expression or activity of RGL3, or alternatively, an agonist may be used in a method for competitive binding assays, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

18. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21.

22. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157

OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

25. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
5/29/03

ARDIN H. MARSCHEL
PRIMARY EXAMINER